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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,893	04/26/2001	Marek Naruszewicz	204742US0PCT	5028

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EXAMINER	
MARX, IRENE	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 08/19/2002 14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/787,893	Applicant(s) Naruszewicz
	Examiner Irene Marx	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 8, 2002* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1 and 15-37* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1 and 15-37* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The application should be reviewed for errors. Error occurs, for example in the repetition of "is administered" in claim 20.

The amendment filed 7/8/02 is acknowledged. Claims 11 and 15-37 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 15-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is vague, indefinite and confusing in the recitation of "reducing the levels of at least one oxidative stress factor in the blood of a mammal". The "reduction" intended cannot be readily ascertained, since the baseline amount is not indicated. Is it 0.000001%, 0.1%, 10%, etc.? How is this assessed?

Claim 24 is vague, indefinite and confusing in the recitation of "increasing the levels of fecal concentration of propionic acid in a mammal". The "increase" intended cannot be readily ascertained, since the baseline amount is not indicated. Is it 0.000001%, 0.1%, 10%, etc.? How is this assessed?

Claim 31 is vague indefinite and confusing in the recitation of "reducing the adhesion of monocytes to endothelial in a mammal". It is assumed that "cells" are intended based on the previously presented claims. Correction is required. In addition the amount of "reduction" intended cannot be readily ascertained, since the baseline amount is not indicated. Is it 0.000001%, 0.1%, 10%, etc.? and how is the reduction assessed in every endothelial cell?

When a word of degree, such as "increasing" or "reducing" is used as a limitation, it is necessary to determine whether the specification provides some standard for measuring that degree. See *Seattle Box Company, Inc. V. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). In this case, the specification does not enable one skilled in the art

to reasonably establish what may be construed as being within the metes and bounds of the word of degree. Therefore, one of ordinary skill in the art would not be apprised as to the claimed invention's scope when the claims are read in light of the specification. See *Ex parte Oetiker*, 23 USPQ2d 1641.

The claims are vague and indefinite in the recitation of an "effective amount of *Lactobacillus plantarum* 299v", respectively, "effective amounts of oatmeal gruel comprising *Lactobacillus plantarum* 299v". The amounts of the active ingredient intended cannot be readily determined in this context, for the various applications recited, even when reading the claims in light of the specification. It is unclear whether the "effective amount" depends on the condition to be treated and/or on the nature of the mammal treated. Are the bacteria viable?

It is unclear how the "effective amount" is to be determined for any and all mammals, regardless of their size, including a mouse, rat, dog, cat, lion, rhinoceros or human. No guidance is provided in the specification in this regard. In addition, it is unclear whether the "effective amount" for such a mammal, in addition, depends on a specific inflammatory condition, a particular symptom, or the amount of material smoked. In claims 21, 28 and 35, does the "heavy smoker" smoke cigarettes, cigars, marihuana, etc.? Also it is unclear how the level of "heavy" with regard to smoking is to be assessed in order to properly identify the mammal in need of administration of the claim designated invention. Is it 10, 20, 30, 40 or more cigarettes or cigars an hour, a day or a week? No clear definitions or identification of the subjects tested are provided in the as filed specification. No new matter may be added.

Claims 23, 30, 37 are vague, indefinite and confusing in characterizing "cancer" as in inflammatory disease. The basis for this characterization is at least uncertain. Also the nature of "rheumatic disease" in this context is unclear.

Claims 19, 26 and 33 are confusing in that the length of the treatment is not set forth. Is it one day, 3 days, 3 months, a year, forever? Claims 20, 27 and 34 are confusing in that the dosage of the material administered is not set forth with any particularity.

Therefore, the metes and bounds of the claims are undefined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11, 15-18, 22-25, 29, 31-32, and 36-37 are/remain rejected under 35 U.S.C. 102(b) as being anticipated by Bengmark et al. for the reasons as stated in the last Office action and the further reasons below.

The claims are to be directed to the use of *L. plantarum* 299v to reduce oxidative stress factors in blood, to increase the levels of fecal concentration of propionic acid and to reduce adhesion of monocytes to endothelial cells.

The reference discloses the administration of *L. plantarum* 299v to humans. See, e.g., Table 1, wherein 299v is reported as A1. The reduction of oxidative stress factors in blood, increase levels of fecal concentration of propionic acid and reduction of adhesion of monocytes to endothelial cells are inherent properties of the administration of the microbe to the individual. Every mammal is in need of at least reduction of the levels of at least one oxidative stress factor in blood, increase in levels of fecal concentration of propionic acid and reduction of adhesion of monocytes to endothelial tissue, which are all related to ageing, which is common to all mammals. It reasonably be presumed that the subjects in the "expert panel" in the reference suffered from at least some symptoms of inflammatory disease. In addition, it is more than likely that they also suffered from atherosclerosis at least to some extent at the time of testing.

If the active step of the method is the same and the subject is the same, then the claimed method can be anticipated or made obvious by the prior art, even if the prior art does not recognize or appreciate this mechanism as long as the compound administered, dosage, mode of administration, subject, etc. are the same as in the method disclosed in the prior art.

If this were not so, one patent might issue with a one step claim of administering the compound to a subject in order to empirically treat a specific disease which is result of a contemporaneously unknown, disordered mechanism or pathway; and, then upon later discovery

of the mechanism of the disorder, another patent could issue with a one step claim directed to the administration of the same compound to the same subject in order to modulate the specifically disordered mechanism or pathway. This would lead to multiple patents with essentially the same invention being patented, merely being couched in different words.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

It is not relevant to the analysis of the claimed method that the reference makes no mention of (reducing or increasing levels of particular substances etc.). Discovery of a new benefit for an old process does not render the old process patentable. In re Woodruff, 919 F. 2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). Merely because the reference did not have one of applicant's purposes in mind when the (drug was administered) does not alter the drug's physiological activity. In the context of an anticipation rejection, the Federal Circuit stated, "Where, as here, the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the results." Mehl/Biophile Int'l Corp. v. Milgraum, 192 F. 3d 1362, 1366, 52 USPQ2d 1303, 1307 (Fed. Cir. 1999).

" To invalidate a patent by anticipation, a prior art reference normally needs to disclose each and every limitation of the claim. See Standard Havens Prods., Inc. v. Gencor Indus., Inc., 953 F.2d 1360, 1369, 21 USPQ2d 1321, 1328 (Fed. Cir. 1991). However, a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it. See id.; Verdegaal Bros., Inc. v. Union Oil Co. of Cal., 814 F.2d 628, 630, 2 USPQ2d 1051,1053 (Fed. Cir. 1987). Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. See *In re* King, 801 F.2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986). Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. See Titanium Metals, 778 F.2d at 780. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. See id. at 782. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's

functioning, does not render the old composition patentably new to the discoverer. See id. at 782 ("Congress has not seen fit to permit the patenting of an old [composition], known to others . . . , by one who has discovered its . . . useful properties."); Verdegaal Bros., 814 F.2d at 633.

This court's decision in Titanium Metals illustrates these principles. See Titanium Metals, 778 F.2d at 775. In Titanium Metals, the patent applicants sought a patent for a titanium alloy containing various ranges of nickel, molybdenum, iron, and titanium. The claims also required that the alloy be "characterized by good corrosion resistance in hot brine environments." Titanium Metals, 778 F.2d at 776. A prior art reference disclosed a titanium alloy falling within the claimed ranges, but did not disclose any corrosion-resistant properties. This court affirmed a decision of the PTO Board of Appeals finding the claimed invention unpatentable as anticipated. This court concluded that the claimed alloy was not novel, noting that "it is immaterial, on the issue of their novelty, what inherent properties the alloys have or whether these applicants discovered certain inherent properties." Id. at 782. This same reasoning holds true when it is not a property, but an ingredient, which is inherently contained in the prior art. The public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate. The doctrine of anticipation by inherency, among other doctrines, enforces that basic principle." See Atlas Powder Co. v. IRECO Inc. 51 USPQ2d 1943 (Fed. Cir. 1999).

Thus, a reference may be anticipatory if it discloses every limitation of the claimed invention either explicitly or inherently. A reference includes an inherent characteristic if that characteristic is the "natural result" flowing from the reference's explicitly explicated limitations. Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

In the instant case, the "reducing the levels of at least one oxidative stress factor in the blood of a mammal"; "increasing the levels of fecal concentration of propionic acid in a mammal" and/or "reducing the adhesion of monocytes to endothelial in a mammal" flows from

the administration of *L. plantarum* 299v to humans, who are mammals in need of treatment. Thus applicants are incorrect in arguing that the anticipatory rejection is improper.

See *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993) The board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of *P. cepacia*. A US patent to Dart disclosed inoculation using *P. cepacia* bacteria for protecting the plant from fungal disease. Dart was silent with regard to nematode inhibition, but the Board concluded that nematode inhibition was an inherent property of the bacteria, and therefore of the method as disclosed by Dart.

With regard to Rapoport, it is noted that the instant case can be distinguished from that decision in that in the decision there is a clear difference in the timing of administration of the medicament and the purpose of administration, which is for a specific ailment, i.e., sleep apnea. This cannot reasonably be equated with the claimed processes herein, having no particular requirements or disclosure relating to dose to be administered and wherein the processes are directed to broad effects, such as "**reduction** of levels of oxidative stress factors in blood" "**increase** in the fecal concentration of propionic acid" and "**reduction** of the adhesion of monocytes to endothelial".

The absence of specific dosages, administration protocol, timing of administration and the sweeping and all-encompassing the nature of the intended "oxidative stress factors in blood" and the increases and reductions intended precludes arguments that the intended effects are specific in nature, as in Rapoport, or that administration for any purpose whatsoever would not meet the broad recitations in the claims.

Therefore the rejection is deemed proper and it is adhered to.

Claims 19-21, 26-28 and 33-35 are free of the art of record.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION is MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196 .

Irene Marx
Primary Examiner
Art Unit 1651